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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------------------|------------------------|
| 10/681,580 | 10/06/2003 | Glenn H. MacKal | 380804.00116 | 6851 |
| 34802 7590 01/28/2008 HOLLAND & KNIGHT LLP ATTN: STEFAN V. STEIN/ IP DEPT. POST OFFICE BOX 1288 TAMPA, FL 33601-1288 | | | EXAMINER CARTAGENA, MELVIN A | |
| | | | ART UNIT 3754 | PAPER NUMBER |
| | | | MAIL DATE 01/28/2008 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--|--------------------------------------|--|
| Office Action Summary | Application No. 10/681,580 | Applicant(s) MACKAL ET AL. | |
| | Examiner Melvin A. Cartagena | Art Unit 3754 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,6 and 9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,6 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 8, 2007 has been entered.

Claim Objections

2. Claims 3 and 5 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 3 depended from canceled claim 2; for examining purposes claim 3 has been examined as dependent from claim 1.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 5 recites that the undulating configurations are out of phase with each other. This is shown

in Figs. 3A-3C (compare with Figs. 2A-2C). However, independent claim 1 now requires the upper and lower surfaces to be transverse to an axis of the pill and at least one of the surfaces including multiple undulating configurations extending parallel to a plane of the surface (which is shown in Figs. 4A-4C with the undulating configurations in phase with each other). So the originally filed application does not have support for the embodiment shown in Fig. 4A-4C in combination with the out-of-phase undulations. This is a new matter rejection.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 3, 5, 6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 3,308,494 to R. J. Licher.

Licher discloses an automatic inflator comprising a body (see Fig. 3) for receiving a dissolvable annular pill (53, 163, 164, and other ref. nos. in other embodiments) including an upper surface and a lower surface with an undulating configuration in various embodiments (note also the serrations and apertures in various embodiments). Licher also discloses the peaks and troughs (claim 2), multiple surfaces with undulations (claim 3), undulations out of phase with each other (claim 5, see Fig. 11), the undulations extending radially (claim 6), and a center hole (claim 9). Licher no longer anticipates the claims, as the surfaces no longer have multiple undulating configurations extending parallel to the plane of the surface that is transverse to an axis of the pill.

Therefore, Licher does not disclose the exact shape of the pill as set forth in the amended claims. However, Licher also recognizes that the shape of the dissolvable pill is a results effective variable, i.e. a variable that achieve a recognized result. In the instant case, the shape is chosen to have a greater surface area so that the pill dissolves quickly (see column 3, lines 29-43). If one of ordinary skill in the art wants the pill to dissolve more quickly, they will choose a shape with greater surface area (i.e. more undulations) and if the artisan wants the pill to dissolve less quickly, they will choose a shape with a lesser surface area. Since the prior art recognizes the shape as a results-effective variable, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have chosen the shapes set forth in the claims, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (see MPEP 2144.05).

Response to Arguments

8. Applicant's arguments filed November 8, 2007 have been fully considered but they are not persuasive. Applicant argues that Figs. 2A, 2B and 2C shows an undulating out of phase configuration; however, there is no original disclosure of combining the embodiments of Figs. 2A-2C and that of Figs. 4A-4C, as claimed. In response to applicant's argument that the ribs of Licher's weaken the ability to withstand compression forces, it is noted that claim 1 requires the pill to provide sufficient strength to preclude actuation of the actuator until the undulating configuration is wet, the pill in the device of Licher preclude actuation of the actuator until the pill is wetted as required by the claim.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melvin A. Cartagena whose telephone number is (571) 272-4924. The examiner can normally be reached on T-F (7:30AM to 6:00 PM).

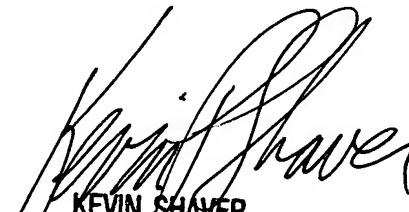
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on (571) 272-4720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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